



Affidavit by Marek Elbaum

I certify that I am an inventor of U.S. Patent Application 09/032,450 filed 02/27/98.

I certify that I am skilled in the art of machine vision and in the art of statistical pattern recognition. I certify that for 20 years I was employed by Riverside Research Institute - an offspring of Columbia University's Electronics Research Laboratory. I have over 60 papers in peer-reviewed literature, among them 2 papers on neural networks, and about 4 issued patents.

In support of my contention that the above identified patent application is novel and useful over the prior art, please enter into the record the enclosed reprint from Discover Magazine (July, 1998). I certify that the embodiment of the above identified application was chosen among "45 of the most innovative technologies and people at work today" by the Discover awards Awards for Technical Innovation. I certify that for the above identified embodiment I was awarded the 1998 \$100,000 Christopher Columbus Foundation (an independent federal government agency established to encourage and support new discoveries) award which is "bestowed on a living American who has made a discovery that has the potential to make a significant and beneficial impact on society.

I certify that the research for the embodiment of the above identified application (now called MelaFind™) was supported with 4 SBIR (Small Business Innovation Research) grants from the NIH/National Cancer Institute, awarded to us competitively, totaling 1.6 million dollars.

Please enter also the enclosed editorial from the journal Skin Research and Technology, (7pp), an article from Dermatology Times (3pp), and an article from Business Week (1 page) in support of the innovativeness and business success of MelaFind™.

Evidence of commercial success is difficult to produce in the few years that a patent is prosecuted because of the time the FDA requires to certify medical instrumentation and procedure. To date, only one MelaFind™ system has been sold to a Melanoma clinic in Washington. Three of the instruments have been tested for over a year at clinical centers (Harvard and NYU Medical schools, and in the Skin Cancer and Associates location in Plantation, Florida, which is one of the largest melanoma clinics in the USA) as part of phase III studies for FDA pre-market approval (PMA). However, as evidence of such commercial success, I certify that the company which is introducing MelaFind™ to the market, Electro-Optical Sciences, of Irvington, NY, of which I am president and largest stockholder, has attracted \$1.25 million dollars in private capital investment.

I certify that the current blind test with the MelaFind™

classifier on the most difficult cases facing skin cancer specialists, the differentiation between early melanoma and look-alike benign nevi was: 95% sensitivity and 61% specificity on 95 lesions (20 melanomas and 75 nevi). These lesions were biopsied by the oncologists participating in our clinical studies because they thought they were melanomas. This classifier was trained with 300 lesions (75 melanomas, 225 nevi) and was designed to maximize specificity (which was 75%) under the constraint of 100% sensitivity. The blind test results are consistent with the design of the classifier, given the small size of the training and testing sets. We expect that, as the database for the training increases, the blind test results will improve.

I certify that paper by Bostick cited by the Examiner uses a neural network classification, which is fundamentally different from the method of MelaFind™. The neural network starts with the weights from a random number generator. Consequently, neural nets tend to introduce errors when the training set is small. There is no theory that relates precisely what error is introduced by the classifier as a function of the size of the training set. Consequently, the neural networks of identical architectures trained on the identical training sets may produce widely different results. This is not the case for our classifiers that do not use initial random weights.



(signed) Marek Elbaum
President, Electro-Optical Sciences, Inc.